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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,613

12/13/2006

Toshiya Kai

NPR-193

5015

20374 7590 03/30/2009

KUBOVCIK & KUBOVCIK

SUITE 1105

1215 SOUTH CLARK STREET

ARLINGTON, VA 22202

EXAMINER

ARNOLD, ERNST V

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

03/30/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,613	Applicant(s) KAI ET AL.	
	Examiner ERNST V. ARNOLD	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendments filed on 12/11/08 have narrowed the scope of the subject matter from open language (comprising) to closed language (consisting of) in independent claim 1, for example. This has necessitated a new search and new ground of rejection. Accordingly, the Action is FINAL.

Claims 1-9 are pending and under examination.

Withdrawn rejections:

Applicant's amendments and arguments filed 12/11/08 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn. Applicant's amendment's have overcome the rejections of record and those rejections are withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5, 6, 7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Veltman (US 4756838).

Veltman discloses a method of making a dry dialysate product (Abstract and claims 1-7). Finely divided anhydrous sodium bicarbonate is mixed with a granular composition of sodium chloride, magnesium chloride, calcium chloride and lactate, or

Art Unit: 1616

gluconate ions (salt of an organic acid) to form a free flowing granular composition (claims 1 and 4). Vaporizing the water reads on drying (claim 1). The product size is in the range of -20 to +100 mesh (column 3, lines 40-41). Since 100 mesh is about 149 microns then instant claims 1 and 6 are anticipated. Sodium acetate is optional and can be replaced by another component **such as** sodium lactate or sodium gluconate (column 12, lines 10-32). Please note that “such as” does not limit the number or types of salts of organic acids that can be added. Various sizes of the granular product are disclosed (column 26, lines 37-60). A chemically homogenous material is made by the process consisting essentially of an intimate admixture of the salts thus anticipating instant claim 7(claim 1). A spray dryer/fluid bed dryer is used to make the product as well as crushers and granulators (Figures 1-3; column 27, lines 7-67; and column 29, lines 20-25). Veltman discloses distributing a solution of salt over the surfaces of the salt granules thus coating the granules (column 20, example 12). Applicant teaches using spray drying techniques with fluidized bed granulator (page 29 example 7). The Examiner concludes that the since the techniques used by Veltman and the instant Application are the same then the plurality of particles of Veltman are coated with the salt and agglomerated. Therefore, instant claims 3, 8, and 9 are anticipated. Veltman teaches using acetic acid to adjust the pH of acetate containing solutions thus establishing the use of the appropriate acid (acetic acid) to balance the pH of solutions with the corresponding anions (acetate) (column 18, example 8 and column 19, lines 1-5).

Art Unit: 1616

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Veltman (US 4756838) in view of Kai et al. (US 2002/0061338).

Applicant claims a solid pharmaceutical preparation for dialysis, consisting of the following two solid pharmaceutical preparations: a solid pharmaceutical preparation (A) having an average particle size of about 100 μm to 1,500 μm and consisting of one or more electrolytes selected from the group consisting of sodium chloride, calcium chloride, magnesium chloride, and potassium chloride and an organic acid other than acetic acid and/or a salt of the organic acid; and a solid pharmaceutical preparation (B) containing sodium bicarbonate; and methods of making the composition.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The reference of Veltman is discussed in detail above and that discussion is hereby incorporated by reference.

Kai et al. teach a solid preparation for dialysis and methods of preparing a double preparation type sodium bicarbonate solid preparation (Abstract and claims 1-9). The first composition has core particles including **sodium chloride** and a coating layer of one or more electrolytes and the second composition comprises a sugar and an acid (Abstract). The first composition with the core particles of sodium chloride coated with an electrolyte such as **calcium chloride** has an average particle diameter of the granules is 300 to 1700 microns and is mixed with the second composition (claims 1 and 6). The specification discloses a limited list of acids including acetic acid, hydrochloric acid, lactic acid, **citric acid** and oxalic acid and the like ([0034]). Thus a single composition comprising core particles coated with an electrolyte and an acid is disclosed. Kai et al. teach a sodium bicarbonate solid preparation in combination with the composition of claim 1 (claim 7) wherein the acid can be hydrochloric or lactic or citric or oxalic acid. Since the ingredients are exactly the same as instantly claimed then a plurality of them would intrinsically be bound together and the organic acid would be uniformly distributed within the particles.

Kai et al. disclose two different methods of making the solid preparation. In the first method (claim 8) Kai et al. disclose spraying an aqueous solution of electrolyte containing, for example, magnesium chloride, unto core particles of sodium chloride and then drying and a second step of spraying core particles of a sugar to obtain a second

Art Unit: 1616

composition and a third step of mixing the first and second composition with an acid to obtain a solid preparation.

Kai et al. disclose a second method in claim 9 the difference being that the first composition is mixed with an acid first and then mixed with the second composition comprising the sugar to obtain a solid preparation for dialysis. Kai et al. disclose in the specification that the acid can be solid citric acid, which by the nature of it being a solid, will also be a particle ([0034]). It is the Examiner's position that since the materials are the same and the method steps of spraying and drying are the same as instantly claimed then the method of Kai et al. intrinsically granulates the material. Evidence of granulation is provided in claim 6.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Veltman is that Veltman do not expressly teach mixing particles of citric acid in the composition for dialysis and the method of making the composition for dialysis. This deficiency in Veltman is cured by the teachings of Kai et al.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

Art Unit: 1616

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add particles of the solid citric acid, as suggested by Kai et al., to the composition of Veltman and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Veltman teaches adding the corresponding acid to the anion (acetic acid with acetate anion, for example) and in the case where lactate or gluconate or citrate ions are used then the corresponding acids would be used. Kai et al. teach that these are known organic acids for use in dialysis compositions and so the use of citric acid in the composition of Veltman would have been obvious at the time of the invention. Furthermore, isocitrate is a homolog of citric acid and would be expected to have the similar properties of citric acid and would be obvious to one of ordinary skill in the art, in the absence of evidence to the contrary.

From MPEP 2143: "All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art. *KSR*, 550 U.S. at ___, 82 USPQ2d at 1395; *Sakraida v. AG Pro, Inc.*, 425 U.S. 273, 282, 189 USPQ 449, 453 (1976); *Anderson 's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 62-63, 163 USPQ 673, 675 (1969); *Great Atlantic & P. Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152, 87 USPQ 303, 306 (1950).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Art Unit: 1616

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ernst V Arnold/
Examiner, Art Unit 1616